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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHANDRA, GYAN	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,813	SIERRA-HONIGMANN, ROCIO M.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-9 and 11-13, drawn to an agent, a pharmaceutical composition, and a method of modulating a response in a subject to an angiogenesis-inducing stimulus.

Group 2, claim(s) 10, drawn to a method of wound dressing comprising a pharmaceutical composition capable of inducing transfection of nucleotide sequences encoding leptin or leptin receptor.

Group 3, claim(s) 11, 12 and 14, drawn to a topical composition comprising leptin and VEGF that modulates a response to a subject to an angiogenesis-inducing stimulus.

Group 4, claim(s) 15, drawn to a method of identifying agents that binds to the leptin receptor and upon contacting vascular cells, it induces a morphological change in the vascular cells.

Group 5, claim(s) 16, drawn to a method of identifying that modulates leptin receptor mRNA or protein expression which induces a morphological change in the vascular cells.

Group 6, claim(s) 17, drawn to an antibody that binds with a leptin receptor on a cell that modulates a leptin receptor mediated response.

Group 7, claim(s) 18-20, drawn to a method for promoting the formation, maintenance or repair of a tissue comprising administering an effective amount of agent that stimulates leptin or leptin receptor mediated angiogenic response.

Group 8, claim(s) 21-27, drawn to a method of decreasing the undesired angiogenesis comprising administering an effective amount of agent that decreases leptin or leptin receptor mediated angiogenic response.

Group 9, claim(s) 28, drawn to a method of treating angiogenic and fibrotic retinal diseases comprising administering an effective amount of agent that decreases vascular and fibrotic proliferation.

The inventions listed as Groups 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

I. Group 1, recites the special technical feature of an agent, a pharmaceutical composition, and a method of modulating a response in a subject to an angiogenesis-inducing stimulus, which is not required by other products of Groups 3 and 6.

II. Group 2, recites the special technical feature of wound dressing comprising a pharmaceutical composition capable of inducing transfection of nucleotide sequences encoding leptin or leptin receptor, which is not required by other methods of Groups 4, 5, and 7-9.

III. Group 3, recites the special technical feature of a topical composition comprising leptin and VEGF that modulates a response to a subject to an angiogenesis-inducing stimulus, which is not required by other products of Groups 1 and 6.

IV. Group 4, recites the special technical feature of identifying agents that binds to the leptin receptor and upon contacting vascular cells, it induces a morphological change in the vascular cells, which is not required by other methods of Groups 2, 5, and 7-9.

V. Group 5, recites the special technical feature of identifying agents that modulates leptin receptor mRNA or protein expression which induces a morphological change in the vascular cells, which is not required by other methods of Groups 2, 4, and 7-9.

VI. Group 6, recites the special technical feature of an antibody that binds with a leptin receptor on a cell that modulates a leptin receptor mediated response, which is not required by other products of Groups 1 and 3.

VII. Group 7, recites the special technical feature of promoting the formation, maintenance or repair of a tissue comprising administering an effective amount of agent that stimulates leptin or leptin receptor mediated angiogenic response, which is not required by other methods of Groups 2, 4, 5, and 8-9.

VIII. Group 8, recites the special technical feature of decreasing the undesired angiogenesis comprising administering an effective amount of agent that decreases leptin or leptin receptor mediated angiogenic response, which is not required by other methods of Groups 2, 4, 5, 7 and 9.

IX. Group 9, recites the special technical feature of decreasing the undesired angiogenesis comprising administering an effective amount of agent that decreases leptin or leptin receptor mediated angiogenic response, which is not required by other methods of Groups 2, 4, 5, and 7-8.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A. An angiogenic response modulating agent:

i) leptin

ii) leptin homologue

iii) angiogenic peptide fragment of leptin

iv) idiotypic antibody

v) lepin sensitizer

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

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The following claim(s) are generic: 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (i) leptin. This special feature is not shared by any other species.
The special technical feature of (ii) leptin homologue. This special feature is not shared by any other species.
The special technical feature of (iii) angiogenic peptide fragment of leptin. This special feature is not shared by any other species.
The special technical feature of (iv) idiotypic antibody. This special feature is not shared by any other species.
The special technical feature of iv) lepin sensitizer. This special feature is not shared by any other species.

B. Nucleic acid transfection inducer:

vi) leptin secreting cells

vii) viral agents

viii) chemical compound

ix) biological compound

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

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The following claim(s) are generic: 10.
The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (vi) leptin secreting cells. This special feature is not shared by any other species.
The special technical feature of (vii) viral agents. This special feature is not shared by any other species.
The special technical feature of (viii) chemical compound. This special feature is not shared by any other species.
The special technical feature of (ix) biological compound. This special feature is not shared by any other species.

C. Wound heeling modulator:
A number of wound healing modulators are listed in claim 24. The special technical feature of each modulator is not shared by other species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 21-22.

D. Additives:

Claim 27 recites a number of additives for treating wound healing.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 21-22.

If Applicant selects Group 1, one species from the angiogenic response modulating agent group must be chosen to be considered fully responsive. If Applicant selects Group 2, one species from the nucleic acid transfection inducer group must be chosen to be considered fully responsive. If Applicant selects Group 8, one species from the wound heeling modulator group and one species from the additive group must also be chosen to be considered fully responsive.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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